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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,539	05/01/2001	Lars Bjorck	100084.415US	4148

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,539

Applicant(s)

BJORCK ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>g</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's response to restriction and amendment filed on 9/30/02 (paper No 13) is acknowledged. Claims 1-18 and 20-22 have been canceled. New claims 23-39 have been added. Claims 23-39 are pending in the application.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority applications United Kingdom 9823975.9 under 35 U.S.C. 119(a)(d). However, the office has not received the certified copy of United Kingdom 9823975.9. Applicant is advised to submit the certified copy in order to get foreign priority.

Drawings

3. The drawings are not accepted by the draftsman under 37 C.F.R. 1.84 or 1.152. Applicant should comply with the objections to the drawings as set forth in Form- 948 (Draftsman's Notice) mailed with this Office action.

Information Disclosure Statement

4. Information Disclosure Statement filed on 5/01/01 (Paper # 8) is acknowledged and a signed copy is attached to this Office action.

Election

5. Applicant's election of Group I claims 1-12 and 18 (polypeptide) with respect to SEQ.ID.NO: 6 in Paper No 13 (9/30/02) without traverse is acknowledged. New claims 23-39, limited to elected specific sequence SEQ.ID.NO: 6 have been submitted to replace the claims 1-12 and 18 and therefore are under examination as an elected invention.

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Specification Informalities

6. Page 14, line 27 refers to worldwide web address. The worldwide web address can be readily changed with rapidly changing technology and therefore, may not be available to the public. Therefore, applicant is advised to amend the specification and use some other means to recite the genome sequence. Appropriate correction is required.

Title: Applicant has amended the Title (paper # 7) to "STREPTOCOCCAL ALPHA ZM BINDING PROTEIN". However, it is noted that the invention is related to "STREPTOCOCCAL ALPHA 2 M BINDING PROTEIN". Therefore, the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "STREPTOCOCCAL ALPHA 2 M BINDING PROTEIN".

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23-39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The product, a protein as claimed, has the same characteristics as that found in nature because the protein can be obtained from any source such as human body etc. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations, which would distinguish the characteristics and utility of applicant's product as enabled in the specification from the utility of the product as it exists in nature. It is further suggested that such limitation include the terminology "essentially purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what

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applicant's protein is "free of" relative to the natural source, which imparts a distinct utility to the claimed product. For relevant case law see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

Claim Rejections - 35 USC 112, first paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 23-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein that is capable of binding to α_2 M and that comprises the amino acid sequence of SEQ.ID.NO: 6 does not reasonably provide enablement for a functional variant thereof, functional variant with 75% and 78% homology to amino acids 59 to 86 of SEQ.ID.NO: 6, peptide fragments comprising 6, 15 and 20 amino acids of SEQ.ID.NO: 6, variants with at least 75% and 78% homology to amino acids 59 to 86 of SEQ.ID.NO: 6 and protein or functional variant comprising one or more tandem repeats. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is not enabled for a functional variant thereof or functional variant with 75% and 78% homology to amino acids 59 to 86 of SEQ.ID.NO: 6 or peptide fragments comprising 6, 15 and 20 amino acids of SEQ.ID.NO: 6 or variants with at least 75% and 78%

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homology to amino acids 59 to 86 of SEQ.ID.NO: 6 because the specification is totally silent. If it is unclear to one skilled in the art what are those functional equivalents or sequences are embraced by the claim since the specification lacks the algorithm and parameters used to determine percent identity or derivatives of fragments.

The specification is silent in what changes have been made to SEQ.ID.NO: 6 to obtain the above functional variants. It is well known that for proteins, for example, even a single amino acid change can destroy the function of the biomolecule. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Further, specification is silent on how to make these proteins with sequence homology or variants or fragments. What changes would have an adverse effect on the function of this peptide is not predictable. It is known in the art that derivatives or variants, which are obtained by substitutions, deletions, or modifications of the amino acids of a protein, alter the function of the protein. The amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex (Bowie et al. Science, Vol. 247: 1990; p. 1306; p. 1308) and is well outside the realm of routine experimentation.

Claim Rejections - 35 USC 112, s cond paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 23-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the abbreviation " $\alpha_2 M$ " is used without definition upon their first appearance in the claims.

Claims 1 and 29 are indefinite because it is not clear what are functional variants? As written it is difficult to understand the metes and bounds of "functional variants".

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 23- 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Lammler et al 1986 (Zbl.Bakt.Hyg A 261, 161-166)

Claims are directed to a protein or peptide that is capable of binding to α_2 Macroglobulin and that comprises the amino acid sequence of SEQ.ID.NO: 6 or functional variants or variant is from *S.pyogenes* other than SF 370.

Examiner is viewing the functional variant as any protein or peptide that is capable of binding to α_2 macroglobulin.

Lammler et al disclose ten of the 11 streptococcal cultures of serological group A, T typ 4 possessing antigen (T4) bound to α_2 macroglobulin (see abstract, Table 1). Further, the prior

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art disclose that only one strain 71-715 did not bind to α_2 macroglobulin but other 10 strains including *S.pyogenes* strain 71-727 bound to α_2 macroglobulin (see page 163 under binding of plasma proteins). Thus the prior art reads on claim 28 as well. In the absence of evidence to the contrary the disclosed prior art streptococcal proteins comprise amino acid sequence of SEQ.ID.NO: 6. Since the Office does not have the facilities for examining and comparing applicants' claimed protein with the T4 antigen of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed protein and the T4 antigen of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

14. Claims 23- 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Chhatwal et al (*J.Bacteriology*, 169; 3691-3695).

The claims are discussed supra.

Chhatwal et al disclose streptococcal cultures of serological group A, including *S.pyogenes* strain A8189 bound to α_2 macroglobulin (see abstract, Table 1 and figure 3). Further, the prior art disclose streptococcal lysates and purified proteins bind to α_2 macroglobulin as well as antibodies to α_2 macroglobulin indicating that the protein binds to α_2 macroglobulin (see figure 4). *S.pyogenes* strain A8189 bound to α_2 macroglobulin (figures 1-4) since this strain is not SF 370, would read on claim 28. In the absence of evidence to the contrary the disclosed prior art streptococcal proteins comprise amino acid sequence of SEQ.ID.NO: 6. Since the Office does not have the facilities for examining and comparing applicants' claimed protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed protein and the protein of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Status of Claims

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

12/2/02.

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